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10/032,658	11/08/2001	Laurie A. Graham	016252-002110US	6842

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EXAMINER

RAMIREZ, DELIA M

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 07/15/2003

(8)

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Applicati n No.

10/032,658

Applicant(s)

GRAHAM ET AL.

Examiner

Delia M. Ramirez

Art Unit

1652

-- The MAILING DATE of this communication appears n the cover sheet with th correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 05 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 36-49 and 78-81 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 36-41, 43-49, 78-81 is/are rejected.
- 7) ☒ Claim(s) 42 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 May 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Status of the Application***

Claims 36-49 and 78-81 are pending.

Applicant's amendment of claims 36, 41-42, 78, 81, and cancellation of non-elected claims 50-77 in Paper No. 11, filed on 5/5/2003 is acknowledged.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

### ***Drawings***

1. The drawings submitted on 5/5/2003 have been reviewed and are objected under 37 CFR 1.84 or 1.152. See attached Notice of Draftsperson's Patent Drawing Review. Applicant is required to submit the drawing corrections within the time period set in the attached Office communication. See 37 CFR 1.85(a). Failure to take corrective action within the set period will result in ABANDONMENT of the application. In addition, if amendments to the specification are needed due to drawing corrections, Applicant is requested to submit such amendments while the case is being prosecuted to expedite the processing of the application.

### ***Claim Objections***

2. Claims 36 and 78 are objected to due to the recitation of "an antifreeze protein of YL-1 (SEQ ID NO: 11). For clarity, it is suggested that the term be replaced with "the antifreeze protein YL-1 ( SEQ ID NO: 11)" or "the antifreeze protein as set forth in SEQ ID NO: 11 (YL-1)". Appropriate correction is required.

***Claim Rejections - 35 USC § 112, First Paragraph***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 36-41, 43-49, 78-81 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the polypeptide of SEQ ID NO: 11, does not reasonably provide enablement for any antifreeze protein which has at least 70% sequence identity to the polypeptide of SEQ ID NO: 11. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

5. This rejection has been discussed at length in Paper No. 9, mailed on 12/3/2002.

6. Applicants argue that in the enablement analysis, the subject matter claimed should be considered as a whole and parts should not be analyzed individually. Specifically, Applicants submit that the rejection is improper since the Examiner has only focused on the unpredictability of the art in regard to assigning function based on sequence comparison and has not considered additional limitations as recited in the claims such as molecular weight, thermal hysteresis activity at a defined concentration, the presence of the motif set forth in SEQ ID NO: 3 and specific binding to an antibody raised against the polypeptide of SEQ ID NO: 11 (YL-1). Applicants further submit that methods to determine sequence identity are set forth in the specification and that one can identify 70% sequence homologs of the polypeptide as set forth in SEQ ID NO: 11. Applicants argue that one can use the methods of the specification to make and

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use polypeptides which meet all the other requirements of the claims without undue experimentation. Furthermore, Applicants submit that the specification discloses the structure of 5 antifreeze proteins, therefore relevant working examples are not lacking. It is Applicant's conclusion that one of skill in the art can make and use polypeptides having the characteristics recited in the claims when combining the teachings of the specification and the information known in the art without undue experimentation.

7. Applicant's arguments have been fully considered but are not deemed persuasive to overcome the rejection. While it is agreed that (1) the claims recite other limitations in regard to the claimed polypeptides in addition to the structural limitation, (2) determining % identity is routine in the art, and (3) the specification discloses 5 antifreeze proteins, the Examiner disagrees with Applicant's contention that the full scope of the claims is enabled and that other limitations in the claims were not considered in the enablement analysis. As indicated in previous Office Action Paper No. 9, mailed on 12/3/2002, the specification fails to disclose which are the amino acids which can be substituted, deleted or inserted and obtain a 70% structural homolog of the polypeptide of SEQ ID NO: 11 with the desired functional characteristics as recited in the claims, i.e. antifreeze function and a thermal hysteresis activity of more than 1.5 C at a concentration of 1 mg/mL. In addition, while the specification discloses a 12 amino acid motif (SEQ ID NO: 1) and a 16 amino acid N-terminal motif (SEQ ID NO: 3), the specification fails to disclose whether (1) these motifs are related to antifreeze function or thermal hysteresis, or (2) how many and/or which of these motifs are required to display antifreeze function and thermal hysteresis activity of more than 1.5 C at a concentration of 1 mg/mL. While it is agreed that 5 antifreeze proteins have been disclosed in the instant application, there is no information as to

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which are the structural elements in all these proteins which are required to display antifreeze activity or thermal hysteresis activity as recited or how many motifs should be present to display the recited characteristics. Since the state of the art clearly teaches the unpredictability of determining function based on structural homology, one of skill in the art would require some knowledge or guidance as to which are the structural elements required in a 70% structural homolog of the polypeptide of SEQ ID NO: 11 to have antifreeze properties and a thermal hysteresis activity of more than 1.5 C at a concentration of 1 mg/mL. As such, one of skill in the art cannot reasonably conclude that the invention as claimed is fully enabled.

8. It is noted that this rejection may be obviated by incorporating the structural limitation recited in claim 38, i.e. wherein the antifreeze protein comprises 5 to 12 repeats of the motif set forth in SEQ ID NO: 1", in claims 36 and 78.

#### ***Allowable Subject Matter***

9. Claim 42 appears to be allowable over the prior art of record but is objected to since it depends upon rejected claim 36 and for the reasons set forth above under Claim Objections.

#### ***Conclusion***

10. No claim is in condition for allowance.

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. Applicants are requested to submit a clean copy of the pending claims (including amendments, if any) in future written communications to aid in the examination of this application.


13. Certain papers related to this application may be submitted to Art Unit 1652 by facsimile transmission. The FAX number is (703) 308-4556. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If Applicant submits a paper by FAX, the original copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (703) 306-0288. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (703) 308-3804. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Delia M. Ramirez, Ph.D.  
Patent Examiner  
Art Unit 1652

DR  
July 2, 2003

  
REBECCA E. PROUTY  
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1600